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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,609	05/03/2001	Paul E. Laibinis	MTV-031.01	6015

25181 7590 10/07/2003

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 10/07/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,609

Applicant(s)

LAIBINIS ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-49 is/are pending in the application.
- 4a) Of the above claim(s) 3,7,8 and 20-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,9-19,48 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Response to Arguments

Applicants state that claims 2 and 3 read on the elected species of psoralen as the crosslinking moiety and request clarification as to the withdrawal of claim 3.

In response, claim 3 is withdrawn from consideration since it reads on a linking moiety and does not read on without a linker as in claim 4. Nevertheless, applicants' arguments are moot with the cancellation of claim 2 to which claim 3 depends.

Specification

The objection to the disclosure has been obviated with the amendments to the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-6, 9- and 48-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

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matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The as-filed specification fails to describe a "pairing oligonucleotide sequence that is covalently attached to the target moiety through a linking moiety, wherein said linking moiety terminates chain extension by polymerase". Applicants point support for this claim amendment at page 38 and Figure 3.

A review of the cited sections presents a different concept from the newly presented limitation. The description of the drawings in the specification does not provide a detail description of Figure 3. [Cf. with page 47, last incomplete paragraph and page 51, Example 6]. Thus, the specification fails to provide a written description wherein the pairing oligonucleotide sequence is covalently attached to the **target moiety through a linking moiety, wherein said linking moiety terminates chain extension by polymerase.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1, 5-6, 9-19 and 48-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite as to how the linking moiety terminates the chain extension by a polymerase, especially in the absence of positive support in the specification. Furthermore, this limitation appears to relate to method rather, than a positive characterization of the complex composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly

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or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 5, 6, 9-19 and 48-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Yu (US 6,600,026).

Yu discloses at e.g., col. 2, lines 1-30, FIGS. 1A, 1B and 1C a solid bound array FIG. 1A depicts a target sequence 120 hybridized to a capture probe 100 linked via a attachment linker 106, which as outlined herein may be either a conductive oligomer or an insulator. The electrode 105 comprises a monolayer of passivation agent 107, which can comprise conductive oligomers (depicted as 108) and/or insulators (depicted as 109), and preferably both. FIG. 1B depicts the use of a single capture extender probe 110 with a first portion 111 that will hybridize to a first portion of the target sequence 120 and a second portion that will hybridize to the capture probe 100. FIG. 1C depicts the use of two capture extender probes 110 and 130. The first capture extender probe 110 has a first portion 111 that will hybridize to a first portion of the target sequence 120 and a second portion 112 that will hybridize to a first portion 102 of the capture probe 100. The second capture extender probe 130 has a first portion 132 that will

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hybridize to a second portion of the target sequence 120 and a second portion 131 that will hybridize to a second portion 101 of the capture probe 100. See col. 12, line 31 up to col. 13, line 11; col. 20, line 54 up to col. 24, line 35 and col. 44, lines 36-44. Accordingly, the specific support bound array of Yu disclosing the specific components fully meets the claimed support bound array. The claimed limitation of the linker as being able to terminate chain extension by polymerase will be inherent to the teaching of Yu.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-6, 9-19 and 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Horn et al (6, 465,175) in view of Kuimelis et al (WO 99/51773) for reasons advanced in the last Office action.

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Response to Arguments

Applicants admit that Horn discloses a linking moiety but argue that the linking moiety is in association with a nucleic acid multimer and not in association with the capture extender molecule. It is further argued that the nucleic acid multimer and capture extender molecules appear to be completely separate elements of Horn et al as these terms are separately defined in the specification. Applicants admit that that Horn disclose a linker moiety as ethylene glycol but argue that the linker is used as a means to attach a label to an oligonucleotide probe to create an oligomer-label conjugate.

In response, Horn relies upon U.S. Patent 6,635, 352 (col. 9, line 24) which disclose the use of a linker for the purpose as claimed. Furthermore, whether the linker, ethylene glycol, is used for a different purpose as claimed does not preclude Horn's teaching that ethylene glycol, is known to link two substances.

Applicants argue that Kuimeles fails to cure the deficiencies of Horn. Kuimeles like Horn is argued as failing to teach a linking moiety that covalently attaches a target moiety to a pairing oligo wherein the linking moiety terminates extension by polymerase.

In reply, the response under Horn above is applied. Furthermore, as stated above, it is not clear how the linking

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moiety terminates extension by polymerase in the absence of positive teaching as to how said linker accomplishes such.

The alternative rejection over Guire no longer applies in view of applicants' arguments.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

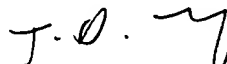
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This application contains claims 3, 7-8, and 20-47 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
September 30, 2003